PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 12287440	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU2003/000944	International Filing Date *(day/month/year)* 25 July 2003	Priority Date *(day/month/year)* 26 July 2002

International Patent Classification (IPC) or national classification and IPC

Int. Cl.[7] A61K 39/015, 39/395; A61P 33/00

Applicant

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH et al

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

   I ☒ Basis of the report

   II ☐ Priority

   III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

   IV ☐ Lack of unity of invention

   V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

   VI ☐ Certain documents cited

   VII ☐ Certain defects in the international application

   VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of the report
19 January 2004	1 November 2004
Name and mailing address of the IPEA/AU	Authorized Officer
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	NICOLE HOWARD Telephone No. (02) 6283 2245

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU2003/000944

I. Basis of the report

1. With regard to the elements of the international application:*

[X] the international application as originally filed.

[ ] the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of

[ ] the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of

[ ] the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:

[ ] the description, pages

[ ] the claims, Nos.

[ ] the drawings, sheets/fig.

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	**NONE**	**YES**
	Claims	**1-65**	**NO**
Inventive step (IS)	Claims	**NONE**	**YES**
	Claims	**1-65**	**NO**
Industrial applicability (IA)	Claims	**1-65**	**YES**
	Claims	**NONE**	**NO**

2. Citations and explanations (Rule 70.7)

CITATIONS

D1 WO 2000/015254 A (Walter & Eliza Hall Institute of Medical Research) 23 March 2000

D2 Romero G et al, "Anti-inositolglycan antibodies selectively block some of the actions of insulin in intact BC3H1 cells, PNAS, February 1990, vol 87, pages 1476-1480

D3 Naik RS et al, "Glycosylphosphatidylinositol anchors of Plasmodium falciparum: Molecular characterization and naturally elicited antibody response that may provide immunity to malaria pathogenesis" Journal of Experimental Medicine, 4 December 2000, vol 192, no 11, pages 1563-1575

D4 Schofield L et al, "Synthetic GPI as a candidate anti-toxin vaccine in a model of malaria, Nature, 15 August 2002, vol 418, pages 785-789

EXPLANATIONS

D1 teaches immunogenic compositions and molecules comprising a glycosylphosphatidylinositol (GPI) inositolglycan domain that are incapable of inducing an immune response directed to a lipidic domain of GPI. In particular the GPI is derived from *Plasmodium*. It further teaches antibodies directed against the molecules and methods of treating and preventing parasitic infections. The document deprives claims 1-65 of novelty and an inventive step.

D2 teaches antibodies generated against inositolglycan linkers prepared by pronase digestion of variant surface glycoprotein (VSG) of *Trypanosoma brucei* wherein the lipid portion was removed and therefore deprives claims 43-45 of novelty and an inventive step.

D3 teaches native (GPI) anchors of *Plasmodium falciparum* and characterizes naturally produced antibodies against them. Although the document broadly teaches these antibodies to be mainly directed against the acylated phosphoinositol portion of GPIs there is no specific suggestion that the exogenous use of the inositolglycan portion of GPI's that are substantially deprived of their lipidic domain can be used to generate an immune response, treat or prevent parasite infections, or used to test for and develop immunological molecules of interest. Claims 1-65 are therefore novel and inventive in light of this document.

D4 was published prior to the international filing date of the present claims but later than the priority date claimed and may be of relevance if the priority of the present claims were determined to be invalid. The document teaches synthetic fragments of GPI glycans as anti-toxin vaccines for malaria.

Claims 1-65 are all considered to be industrially applicable.